PhRMA

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June 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Draft Guidance on Placing the FDA Therapeutic Equivalence Code on Prescription Drug Labels and Labeling [Docket No. 98D-1266]
64 Fed. Reg. 4434 (Jan. 28, 1999); 64 Fed. Reg. 19792 (April 22, 1999)

Pharmaceutical Research and Manufacturers of America (PhRMA) submits these additional comments on the draft guidance that the Food and Drug Administration (FDA) made available on January 28, 1999, concerning the use in prescription drug labels and labeling of the therapeutic rating system established in the FDA Orange Book. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to research on medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA submitted extensive comments on the draft guidance on the date they were due -- March 29, 1999 -- and will submit reply comments to whatever comments are submitted by the generic drug industry during this reopened comment period, which was announced by the FDA April 22, 1999.

PhRMA notes that many of the comments filed during the initial comment period raised objections to the proposed guidance or serious concerns about the impact of the proposed guidance on public health and intellectual property rights. These objections and concerns were voiced by brand name pharmaceutical manufacturers, pharmacists, a nonprofit health organization, trade associations, and an organization of chain drugstores. Only the manufacturers of generic pharmaceuticals voiced strong support for the draft guidance and even they were concerned or confused as to how it would operate in practice.

As we explain below, certain comments made by the generic industry underscore the concerns expressed by PhRMA and others.

One generic manufacturer suggested that the therapeutic equivalence statement should be displayed on the front panel, but that the "disclaimer" identifying the owner of the trademark should be appear separately on a side panel. This

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suggests that the generic manufacturers view the proposed guidance as an opportunity to extract the maximum marketing benefit from a brand name trademark, not to ensure that pharmacists and consumers are better informed.

Another generic manufacturer proposed to modify the therapeutic equivalence statement to read "AB-*rated* to Chicose." Although this phrase more accurately reflects the terms used in the Orange Book, it may be confusing when taken out of the Orange Book context. To the lay person, like the consumer, a "rating" often compares the quality of the rated products or organizations. Consumers are familiar with comparative "ratings" from Consumer Reports, Standard & Poors, Moody's and other rating organizations. Thus, if a consumer were to see the phrase "AB-*rated* to Chicose" on a label, that consumer could misconstrue the rating as possibly being an indication that the generic product is superior to (and not simply the therapeutic equivalent of) a brand name product.

Finally, one comment suggested that the generic manufacturers not only should benefit from the use of the brand name trademarks in the therapeutic equivalence statement, but also should be insulated from liability for errors in labeling. Specifically, the comment suggested that regulatory action should be "reserved for a firm who has a pattern of placing inaccurate codes in the labeling rather than for a firm which makes a simple error on one drug or is slow to change the code after a change appears in the Orange Book." PhRMA opposes the suggestion that FDA limit its policing of pharmaceutical labels and labeling in this way. At a minimum, generic manufacturers should bear full responsibility for not misleading the public.

Sincerely yours,

Matthew B. Van Hook
Deputy General Counsel

cc: Jerry Phillips, CDER (HFD-730)

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